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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/766,883	01/30/2004	Teruaki Itoh	160-406	4015

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EXAMINER

WALLENHORST, MAUREEN

ART UNIT	PAPER NUMBER
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1743

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/766,883

Applicant(s)

ITOH, TERUAKI

Examiner

Maureen M. Wallenhorst

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-5 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☒ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)               | Paper No(s)/Mail Date. ____.  |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>1/30/04</u> .   | 6) <input type="checkbox"/> Other: ____.                                    |

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1. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 250 words. It is important that the abstract not exceed 250 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

3. The abstract of the disclosure is objected to because of the inclusion of legal phraseology such as "comprises". Correction is required. See MPEP § 608.01(b).

4. Claims 2-3 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is indefinite and vague since it is not clear whether or not the specimen container rack is attached to both the carry-in elevator and the rectangular parallelepiped specimen container bucket on the rotor, or whether the rack is simply transported between the carry-in elevator and the specimen container bucket. See this same problem with the recitation of the rack, the carry-out elevator and the container bucket on the rotor. The physical relationships between these recited elements of the apparatus and the transport of these elements to different locations in the apparatus should be made clearer.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459

(1966), that are applied for establishing a background for determining obviousness under 35

U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-2 and 4-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Takeda (JP 2000-84436, submitted in the Information Disclosure Statement filed on January 30, 2004) in view of Miller, Muszak et al and Hubert et al.

Takeda et al teach of a centrifugal separator for performing the centrifugation of a liquid sample in a container. The separator comprises a plurality of rotors or centrifuges 10, 12 which each accommodate a plurality of buckets that hold multiple specimen containers. The apparatus also comprises a rack conveying mechanism 14 that transports a rack holding several specimen containers. The conveying mechanism 14 is provided along a horizontal conveyance line that passes by the centrifuge rotors. A tube transfer mechanism 16 transfers a container between the rack and a bucket on one of the rotors and between a bucket and the rack. The rotors are independently controlled by a controller to operate simultaneously or selectively in a given rotation direction. See Figure 1 in Takeda. Takeda fails to teach that the centrifuge rotors 10, 12 can be vertically stacked upon one another, fail to teach of a rack elevator for vertically

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transporting the racks containing specimen tubes to and from the vertically stacked rotors, and fail to teach that the tube transfer mechanism 16 is a robotic arm device including transfer arms for transferring containers to and from the conveyor and to and from the centrifuge rotors.

Miller teaches of a rotor incubator assembly useful in a clinical analyzer comprising a plurality of rotationally driven rotors 52 and 54 vertically stacked one on top of the other. The rotors are independently driven, and contain stations evenly spaced about the circumference for accommodating sample slides. Miller teaches that such a configuration for the rotors reduces the space or area required for the analyzer without reducing the effective throughput of the analyzer. See Figure 4, lines 44-67 in column 1, lines 61-67 in column 2 and lines 1-20 in column 3 of Miller.

Muszak et al teach of an analyzer elevator assembly for delivering sample containers or slides to one of multiple incubator rotors disposed at different vertical levels. The rotors contain multiple sites disposed circumferentially for supporting specimen containers. The elevator contains means for lowering or raising a support holding multiple specimen containers to the different levels of the vertically stacked rotors. A pusher is also present on the elevator for pushing test elements from the elevator support to the rotors and from the rotors to the elevator support. See Figure 2, lines 64-68 in column 2 and lines 20-46 in column 7 of Muszak et al.

Based upon the combination of Takeda and Miller, it would have been obvious to one of ordinary skill in the art at the time of the instant invention to vertically stack the centrifuge rotors taught in the centrifugal separator of Takeda, similar to the vertically stacked rotors disclosed by Miller, so as to provide a savings in space without reducing the effective throughput of the centrifugal separator, as taught by Miller. When the multiple rotors in the centrifugal separator

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taught by Takeda are arranged vertically, it also would have been obvious to one of ordinary skill in the art to provide a rack elevator, similar to the elevator assembly taught by Muszak et al, for transporting the racks in a vertical direction so as to deliver the racks to and from the vertically spaced rotors in an efficient manner, as taught by Muszak et al.

Hubert et al teach of an automated centrifuge loading and unloading device in the form of a robot arm. The device serves to pick up sample tubes moving along a conveyor line, place them in centrifuge racks or adaptors 14, transport the adaptors 14 from a staging area 40 to a centrifuge 16, and vice versa. A robotic arm 18 has both a container tube gripper 20 for picking up individual test tubes moving along a conveyor, and an adaptor or rack gripper 22 for picking up specimen adaptor racks 14 and transporting them to buckets on the centrifuge. Hubert et al also teach that a cabinet 16 encloses the centrifuge. See Figures 1, 2B, 2B and 5, lines 20-58 in column 2, lines 50-67 in column 3 and lines 40-66 in column 4 of Hubert et al.

Based upon the combination of Takeda and Hubert et al, it would have been obvious to one of ordinary skill in the art to form the tube transfer mechanism 16 in the centrifugal separator taught by Takeda as a robotic arm, similar to the robotic arm structure disclosed by Hubert et al, since Hubert et al teach that such a robotic arm device enables both individual tubes and racks holding multiple tubes to be automatically picked up and delivered into a centrifuge for processing in a quick and efficient manner

8: Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Takeda in view of Miller, Muszak et al and Hubert et al as applied to claims 1-2 and 4-5 above, and further in view of Wada et al (US Patent no. 5,199,937). For a teaching of Takeda, Miller, Muszak et al and Hubert et al, see previous paragraphs in this Office action. Takeda fails to teach that the

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openings on the rotors that accommodate buckets containing multiple specimen tubes have a longitudinal direction that corresponds to the radial direction of the rotors.

Wada et al teach of a centrifugal separator that comprises a disc-like rotor 1 having four recesses or slots arranged radially from a rotation axis of the disc. In each recess or slot is located a specimen container bucket 3 for accommodating a set of four mounted specimen tubes 2. The buckets 3 are supported in the slots by a pair of pins projecting into the slots from the rotor 1. A shaft 11 of the rotor 1 is connected to a motor 6 located below the rotor 1. The buckets 3 have a rectangular parallelepiped frame having a support structure at the top with holes to accommodate specimen tubes 2. See Figure 2 in Wada et al. When the rotor 1 starts rotating, centrifugal force acts on the tubes 2 in the buckets 3, and both the tubes 2 and buckets 3 are swung up radially and outwardly by the centrifugal force, resulting in the liquid content of the tubes flowing outward along the inner peripheral surface of the tubes. See lines 64-68 in column 2 and lines 1-42 in column 3 of Wada et al.

Based upon the combination of Takeda, Miller, Muszak et al, Hubert et al and Wada et al, it would have been obvious to one of ordinary skill in the art to arrange the openings on the rotors taught by Takeda that accommodate buckets containing multiple specimen tubes with a longitudinal direction that corresponds to the radial direction of the rotors since Wada et al teach that such a configuration in a centrifugal separator allows for a smooth circular flow of the liquid content in each of the specimen tubes.

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

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Please make note of: Pang et al, O'Bryan et al, Schinzel, Quinlan et al, Riggs and JP 01-189562 who all teach of different types of automated centrifugal devices.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maureen M. Wallenhorst whose telephone number is 571-272-1266. The examiner can normally be reached on Monday-Wednesday from 6:30 AM to 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden, can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maureen M. Wallenhorst  
Primary Examiner  
Art Unit 1743

mmw

September 19, 2005

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